

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

---

WARNER CHILCOTT COMPANY, LLC,

Plaintiff,

v.

MYLAN INC., MYLAN PHARMACEUTICALS  
INC. and FAMY CARE LTD.,

Defendants.

---

)  
) Civil Action No. 3:11-cv-06844-JAP-DEA  
)  
) (Consolidated with C.A. No. 3:11-cv-07228-  
) JAP-DEA for pretrial purposes)  
)

) *DOCUMENT FILED ELECTRONICALLY*

) Return date: September 3, 2013  
)  
)  
)  
)

---

**BRIEF IN SUPPORT OF DEFENDANTS MYLAN INC., MYLAN  
PHARMACEUTICALS INC. AND FAMY CARE LTD.'S MOTION TO SEAL  
AND FOR REDACTION OF ELECTRONIC TRANSCRIPT**

---

Arnold B. Calmann (abc@saiber.com)  
Jeffrey Soos (js@saiber.com)  
Jakob B. Halpern (jbh@saiber.com)  
**SAIBER LLC**  
One Gateway Center, Suite 1000  
Newark, New Jersey 07102-5311  
T: (973) 622-3333

Timothy H. Kratz (tkratz@mcguirewoods.com)  
Robert L. Florence (rflorence@mcguirewoods.com)  
George J. Barry III (gbarry@mcguirewoods.com)  
Karen L. Carroll (kcarroll@mcguirewoods.com)  
Marcus A. Barber (mbarber@mcguirewoods.com)  
**MCGUIREWOODS LLP**  
1230 Peachtree Street N.E., Suite 2100  
Atlanta, Georgia 30309-3534  
T: (404) 443-5500

**TABLE OF CONTENTS**

	<b><u>Page(s)</u></b>
<b>TABLE OF AUTHORITIES .....</b>	<b>ii</b>
<b>PRELIMINARY STATEMENT .....</b>	<b>1</b>
<b>STATEMENT OF FACTS.....</b>	<b>1</b>
<b>ARGUMENT.....</b>	<b>2</b>
<b>POINT I</b>	
<b>THE APPLICABLE LEGAL STANDARDS FOR A MOTION TO SEAL .....</b>	<b>2</b>
<b>POINT II</b>	
<b>UNDER LOCAL CIVIL RULE 5.3(c)(2)(B), LEGITIMATE INTERESTS</b>	
<b>_Toc274031465WARRANT THE SEALING OF THIS INFORMATION.....</b>	<b>3</b>
<b>POINT III</b>	
<b>UNDER LOCAL CIVIL RULE 5.3(c)(2)(C), SERIOUS INJURY WOULD</b>	
<b>RESULT IF THE CONFIDENTIAL INFORMATION WERE NOT SEALED .....</b>	<b>5</b>
<b>POINT IV</b>	
<b>UNDER LOCAL CIVIL RULE 5.3(c)(2)(D), NO LESS RESTRICTIVE</b>	
<b>ALTERNATIVE IS AVAILABLE.....</b>	<b>5</b>
<b>CONCLUSION .....</b>	<b>6</b>

## **TABLE OF AUTHORITIES**

<b><u>FEDERAL CASES</u></b>	<b><u>Page(s)</u></b>
<u>In re Gabapentin Patent Litigation</u> , 312 F. Supp. 2d 653 (D.N.J. 2004).....	4
<u>Goldstein v. Forbes (In re Cendant Corp.)</u> , 260 F.3d 183 (3d Cir. 2001) .....	2
<u>Littlejohn v. BIC Corp.</u> , 851 F.2d 673 (3d Cir. 1988) .....	2, 3
<u>Miller v. Indiana Hospital</u> , 16 F.3d 549 (3d Cir. 1994) .....	2
<u>Nixon v. Warner Commc’ns, Inc.</u> , 435 U.S. 589 (1978) .....	3
<u>Pansy v. Borough of Stroudsburg</u> , 23 F.3d 772 (3d Cir. 1994) .....	5
<u>Publicker Industrial Inc. v. Cohen</u> , 733 F.2d 1059 (3d Cir. 1984) .....	2, 5
<u>Republic of the Philippines v. Westinghouse Electric Corp.</u> , 949 F.2d 653 (3d Cir. 1991) .....	3
<u>Vista India, Inc. v. Raaga, LLC</u> , 2008 WL 834399 (D.N.J. Mar. 27, 2008) .....	4
<u>Zenith Radio Corp. v. Matsushita Fleet Industrial Co. Ltd.</u> , 529 F. Supp. 866 (E.D. Pa. 1981).....	2
 <b><u>FEDERAL STATUTES</u></b>	
Local Civil Rule 5.3(c) .....	1, 2
Local Civil Rule 5.3(c)(2)(B) .....	3
Local Civil Rule 5.3(c)(2)(C) .....	5
Local Civil Rule 5.3(c)(2)(D) .....	5

21 C.F.R. § 314.430 .....	1, 4
Fed. R. Civ. P. 26 .....	2

**OTHER AUTHORITIES**

Restatement (Second) of Torts § 757 .....	4
---	---

### **PRELIMINARY STATEMENT**

Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Famy Care Ltd. (collectively “Defendants”) respectfully submit this Brief in support of their Motion, pursuant to Local Civil Rule 5.3(c), to Seal and Redact the following portions of the Transcript of the claim construction hearing before District Judge Joel A. Pisano on June 12, 2013 [see ECF No. 88 in Civil Action No. 11-6844 and ECF No. 87 in Civil Action No. 11-7228] (“Transcript”):

- Page 48, lines 5-6: All words between “tastes like clams” and “MR. CONDE”;
- Page 48, lines 8-13: All words between “Your Honor” and “THE COURT”; and
- Page 51, lines 6-10: All words between “palatable flavor” and “THE COURT”.

(collectively, the “Confidential Information”). This information has previously been marked as Highly Confidential pursuant to the Discovery Confidentiality Order entered by the Court in this matter.

As confirmed by the Declaration of Minaksi Bhatt, submitted concurrently herewith, the Confidential Information contains and/or reflects Abbreviated New Drug Application (“ANDA”) information regarding one of the accused products in these matters. This proprietary trade secret and technical information is presently confidential and unavailable to the public, and disclosure of such confidential information could seriously impair and injure Defendants’ competitive posture in the marketplace. Recognizing this potential injury, federal law requires that an ANDA remain confidential. See 21 C.F.R. § 314.430(b)-(d)).

Accordingly, it is respectfully requested that the Court grant Defendants’ Motion to Seal and Redact for the reasons set forth herein.

### **STATEMENT OF FACTS**

Defendants respectfully incorporate herein the factual details set forth in the Proposed Findings of Fact and Conclusions of Law submitted herewith regarding the Confidential

Information sought to be sealed and redacted herein. Those facts demonstrate the basis for sealing and redacting the Confidential Information that is the subject of this motion.

## **ARGUMENT**

### **POINT I**

#### **THE APPLICABLE LEGAL STANDARDS FOR A MOTION TO SEAL**

There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record<sup>1</sup> bears the burden of demonstrating that “the material is the kind of information that courts will protect.” Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus. Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)). This Court has the power to seal where confidential information may be disclosed to the public. In particular, Fed. R. Civ. P. 26(c)(1)(G) provides for the courts’ protection of materials containing “trade secret[s] or other confidential research, development, or commercial information[.]” upon motion by a party, to prevent harm to a litigant’s competitive standing in the marketplace. See Zenith Radio Corp. v. Matsushita Fleet Indus. Co. Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

---

<sup>1</sup> Pursuant to the Court’s Policy on the Electronic Availability of Transcripts of Court Proceedings (Rev. 10/1/10), a party seeking to redact portions of an electronically-filed transcript must file a Motion for Redaction of Electronic Transcript. By its terms, Local Civil Rule 5.3(c) sets forth the standard for deciding such motions.

- (a) the nature of the materials or proceedings at issue;
- (b) the legitimate private or public interest which warrant the relief sought;
- (c) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (d) why a less restrictive alternative to the relief sought is not available.

The Confidential Information that is the subject of this Motion relates to Defendants' commercially sensitive and/or proprietary non-public trade secret and technical information. Specifically, the Confidential Information contains and/or reflects ANDA information regarding the accused product.

## **POINT II**

### **UNDER LOCAL CIVIL RULE 5.3(c)(2)(B), LEGITIMATE INTERESTS WARRANT THE SEALING OF THIS INFORMATION**

Courts have recognized that the public right of access to judicial proceedings and records is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). "Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes." Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)). Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citation omitted).

The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The

presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure.” Id. (citations omitted). As such, a party’s confidential processes, chemical formulas and specifications, and research information should be sealed. Id. at 667-68; see Vista India, Inc. v. Raaga, LLC, 2008 WL 834399, at \*2 (D.N.J. Mar. 27, 2008) (protecting “any formula, pattern, device, or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it”) (ultimately quoting Restatement (Second) of Torts § 757 comment b).

Indeed, information included in an ANDA often consists of trade secrets, and federal law requires that ANDAs remain confidential. See Gabapentin, 312 F. Supp. 2d at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party’s confidential processes, chemical formulas and specifications, and research information should be sealed. Gabapentin, 312 F. Supp. 2d at 667-68.

The private interests at stake in this action warrant the relief sought. Here, plaintiff and defendants – private parties – are in dispute relating to a patent and a generic drug product. Sealing the identified documents as requested herein serves to protect the private proprietary business interests of Defendants, which have legitimate interests in ensuring their confidential and proprietary non-public trade secrets remain undisclosed. If this information were to become publicly available, then Defendants’ competitors could potentially (and likely) use that information in the highly competitive pharmaceutical product marketplace. Therefore, the release of Defendants’ Confidential Information poses a substantial risk of harm to Defendants’ legitimate business interests and competitive position. Indeed, the federal government has recognized this interest by requiring that the ANDA remain confidential.



### **POINT III**

#### **UNDER LOCAL CIVIL RULE 5.3(c)(2)(C), SERIOUS INJURY WOULD RESULT IF THE CONFIDENTIAL INFORMATION WERE NOT SEALED**

This Court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994). Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

If relief is not granted, Defendants' designated highly sensitive and confidential trade secrets will be compromised, exposing them to substantial risks. Unless the Confidential Information is filed under seal and thereby redacted, competitors and others will have access to Defendants' important confidential proprietary trade secrets that ordinarily would not be available to the public, let alone to Defendants' competitors in the highly-competitive pharmaceutical industry. Competitors and others in the marketplace might exploit such information to their advantage and benefit, and to Defendants' unfair detriment.

### **POINT IV**

#### **UNDER LOCAL CIVIL RULE 5.3(c)(2)(D), NO LESS RESTRICTIVE ALTERNATIVE IS AVAILABLE**

Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. This concern must be balanced with the requirement that only the "least restrictive alternative" be utilized to restrict public access to judicial proceedings. Publicker, 733 F.2d at 1073.

No less restrictive alternative to sealing is available because Defendants' request is tailored to seal and redact only that portion of the transcript from which may be discerned the

confidential material discussed during the hearing – specifically, that information containing or relating to its ANDA – the release of which would pose a financial and competitive risk to Defendants. Accordingly, the only way to protect Defendants’ confidential interest is to seal and redact the specific portions of the Transcript identified herein.

### **CONCLUSION**

For the foregoing reasons, Defendants respectfully request that the Court recognize that there is no other remedy available but to seal and redact the Confidential Information as requested above.

Dated: August 9, 2013

Respectfully submitted,

**SAIBER LLC**

*Attorneys for Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Famy Care Ltd.*

s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)

Jeffrey Soos (js@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

**SAIBER LLC**

One Gateway Center, Suite 1000

Newark, New Jersey 07102-5311

(973) 622-3333

Timothy H. Kratz (tkratz@mcguirewoods.com)

Robert L. Florence

(rflorence@mcguirewoods.com)

George J. Barry III (gbarry@mcguirewoods.com)

Karen L. Carroll (kcarroll@mcguirewoods.com)

Marcus A. Barber (mbarber@mcguirewoods.com)

**MCGUIREWOODS LLP**

1230 Peachtree Street N.E., Suite 2100

Atlanta, Georgia 30309-3534

(404) 443-5500